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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,403	01/27/2004	Luiz Belardinelli	02-479-E	3369

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EXAMINER	
CRANE, LAWRENCE E	
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1623	

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12/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,403	BELARDINELLI ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 30, 2007 (amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-8,10-17,19-31,62 and 63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-8,10-17,19-31,62 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claims **2-4, 9, 18 and 32-61** were previously cancelled, no claims have been further amended, the disclosure has not been amended, and no new claims have been added as per the amendment filed August 30, 2007. No additional or supplemental Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Claims **1, 5-8, 10-17, 19-31 and 62-63** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1 and 5** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** at line 11, the term "co-solvent comprises methylboronic acid or borate buffer" is technically inaccurate because "methylboronic acid" is a solid at room temperature (m.p. 91-94 degrees C). Appropriate amendment to reflect the probable role of methylboronic acid as an optional -- solute -- is respectfully requested. See also claim **5** wherein the same error occurs.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant has not responded to the above grounds of rejection except for making the flat statement that "the co-solvent is methylboronic acid or borate buffer." In view of the absence of a clarifying amendment specifying the necessary limitation that either -- methylboronic acid is a solute -- or that -- a solution/buffer comprising methylboronic acid is a co-solvent --, or the like, the above rejection has been maintained.

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under 35 U.S.C. §101 because the claimed compositions lack a demonstrated utility or operable utility in view of applicant's insistence that said compositions must incorporate either a borate buffer/co-solvent and/or methylboronic acid-based buffer or co-solvent, and in view of the recognized lethality of at least one of same at low dosages.

Examiner has also cited of record, and supplied herewith, a copy of a page from Remington's Pharmaceutical Sciences, 18th Edition, wherein borate buffer is disclosed to cause red blood cell lysis and is also disclosed to be a mammalian poison in relative small dosages. In the absence of evidence to the contrary, Examiner presumes that buffers made with methylboronic acid in place of boric acid will be similarly poisonous. In view of the intended intravenous administration of the instant claimed pharmaceutical compositions, it is unclear whether these compositions can be used without the danger of serious injury or possible death to the host unless the quantity of boric acid or methylboronic acid contained therein is specifically limited to quantities known to be non-lethal, and preferably known to be non-damaging to red blood cells at the concentrations or dosages administered. A clarifying disclosure on this subject is respectfully requested along with, if appropriate, claim limitations wherein the toxicological realities of the cited prior art disclosure are recognized.

Applicant's arguments with respect to claims **1, 5-8, 10-17, 19-31 and 62-63** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by newly uncovered relevant prior art.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-11*** of copending Application No. **11/253,322**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of imaging and the alleged active ingredient (CVT-3164) are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question, a showing of unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-30*** of copending Application No. **10/629,368**. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question, a showing of unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***11, 14-27, 29-30, 34 and 36-37*** of copending Application No. **11/070,768**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question, a showing of unexpected results would provide a

basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***2-4*** of U. S. Patent No. **7,109,180** (PTO-892 ref. **A**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3033. Therefore the two applications are directed to substantially overlapping subject matter.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question, a showing of unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***5-8 and 10-22*** of U. S. Patent **7,183,264** (PTO-892 ref. **B**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question, a showing of unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***10-24*** of U. S. Patent No. **7,144,872** (PTO-1449 (#5) ref. **E5**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question, a showing of unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***9, 10 and 16*** of U. S. Patent No. **6,641,210** (PTO-1449 (#3) ref. **A15**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both the application and the patent involve administration of the identical active ingredient,

CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question, a showing of unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***2-4*** of U. S. Patent No. **6,770,634** (PTO-1449 (#3) ref. **A17**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3033. Therefore the two claim sets are directed to substantially overlapping subject matter.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question, a showing of unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***29-31*** of U. S. Patent No. **6,214,807** (PTO-1449 (#1) ref. **A12**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both the application and the patent involve administration of the identical active ingredients, CVT-3033 or CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question, a showing of unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***11-13*** of U. S. Patent No. **6,403,567** (PTO-1449 (#1) ref. **A13**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment in both the application and the patent involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging. Therefore, the instant claims sets are directed to substantially overlapping subject matter.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant has argued that the **'567** patent does not disclose or claim the instant claimed combination of active ingredients and buffer alternatives and therefore, that the instant

rejection is inappropriate, and therefore that this rejection should be withdrawn. Examiner respectfully disagrees.

The disclosure in the paragraphs bridging pages 22 and 23 of the '567 patent's application specification discloses that a buffered pharmaceutical composition incorporating almost any pharmaceutically acceptable salt of one of the two specified active ingredients and any acid is acceptable (e.g. "such as hydrochloric, ..." is open ended language), and does not specifically exclude either borates or methylbononates as either co-solvents or as buffer components.

Applicant argues that the requirement of a borate buffer or methylboronic acid-based buffer in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results in support of unobviousness. Therefore, the above rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***2-4*** of U. S. Application No. **11/588,834** (PTO-1449 (#5) ref. **D5**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3033 . Therefore the two applications are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant has argued that the **'834** application does not disclose or claim the instant claimed combination of active ingredients and buffer alternatives and therefore, that the instant rejection is inappropriate, and therefore that this rejection should be withdrawn. Examiner respectfully disagrees.

The disclosure at the top of page 20 of the '834 application discloses that a buffered pharmaceutical composition incorporating almost any pharmaceutically acceptable salt of one of the two specified active ingredients and any acid is acceptable (e.g. "such as hydrochloric, ..." is open ended language), and does not specifically exclude either borates or methylbononates as either co-solvents or as buffer components.

Applicant argues that the requirement of a borate buffer or methylboronic acid-based buffer in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results in support of unobviousness. Therefore, the above rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***29-31*** of U. S. Application No. **11/522,120** (PTO-1449 (#5) ref. **C5**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3146. Therefore the two applications are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant has argued that the **'120** application does not disclose or claim the instant claimed combination of active ingredients and buffer alternatives and therefore, that the instant rejection is inappropriate, and therefore that this rejection should be withdrawn. Examiner respectfully disagrees.

The disclosure at the top of page 19 of the '120 application discloses that a buffered pharmaceutical composition incorporating almost any pharmaceutically acceptable salt of one of the two specified active ingredients and any acid is acceptable (e.g. "such as hydrochloric,

..." is open ended language), and does not specifically exclude either borates or methylbononates as either co-solvents or as buffer components.

Applicant argues that the requirement of a borate buffer or methylboronic acid-based buffer in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results in support of unobviousness. Therefore, the above rejection has been maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Zablocki et al. (US 6,214,807)** (PTO-1449 ref. **A12**).

Applicant is referred to claims ***1 and 29-33*** wherein adenosine agonists with A_{2A} receptor selectivity are disclosed as part of a pharmaceutical composition and the utility in inducing localized vasodilation for cardiac imaging purposes are disclosed. The compound also known as CVT-3033 may be found at column 20, lines 40-50.

The **CV Therapeutics WO 00/78778** reference (PTO-1449 ref. **B3**) is the PCT equivalent to the above reference and anticipates for the same reasons.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question (see column 16, lines 28-67, especially lines 33-39), a showing of unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

Claims **1, 5-8, 10-17, 19-31 and 62-63** are rejected under 35 U.S.C. §102(e) as being anticipated by **Zablocki et al. (US 6,403,567)** (PTO-1449 ref. **A13**).

Applicant is referred to claims ***1, 8, 10 and 11-13*** wherein the compound, also known as CVT-3164, is disclosed as part of a pharmaceutical composition and as having utility in the imaging of mammalian cardiac circulatory systems.

See also **CV Therapeutics WO 00/78779** (PTO-1449 ref. **B2**) which is the PCT equivalent to the **'567** reference and also anticipates the instant noted claims for the same reasons.

Applicant's arguments filed August 30, 2007 have been fully considered but they are not persuasive.

Applicant argues that the requirement of a borate buffer/co-solvent or methylboronic acid-based buffer/co-solvent in combination with either CVT-3033 or CVT-3164 provides a basis for patentable distinction, but has failed to provide any sworn showing of unexpected results. In view of the generic disclosure of "buffers" as a component part of the pharmaceutical compositions in question (see column 14, lines 58-67), a showing of

unexpected results would provide a basis for withdrawal of this rejection. Examiner encourages applicant to provide the appropriate disclosures, if possible, as his earliest convenience. Since no disclosures of the requested type are presently of record, the instant rejection has been maintained.

The above Office action contains one new ground of rejection and therefore could not be made final.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

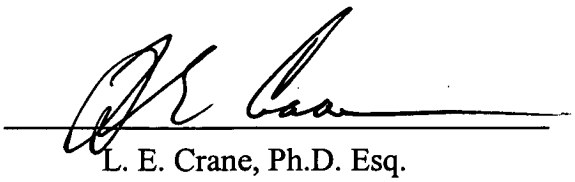
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
12/17/2007



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